



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 7, 2019

David Chi
Regulatory Affairs Manager
Monsanto Company
800 North Lindbergh Blvd.
St. Louis, Missouri 63167

Subject: Labeling Notification per Pesticide Registration Notice (PRN) 98-10 – Removal of alternate brand name and minor label changes
Product Name: COT102 x MON 15985
EPA Registration Number: 524-613
Application Date: October 17, 2018
OPP Decision Number: 546511

Dear Mr. Chi:

The U.S. Environmental Protection Agency (EPA) is in receipt of your application for notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Biopesticides and Pollution Prevention Division (BPPD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The labeling submitted with this application has been stamped “Notification” and will be placed in our records. The alternate brand name Bollgard® 3 has been removed from the product’s records. You must submit one (1) copy of the final printed labeling with the modifications.

Should you wish to add/retain a reference to your company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and is subject to review by the EPA. If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance Assurance.

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If you have any questions, please contact Matt Weiner of my team by phone at (703) 347-0333 or via email at weiner.matthew@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Alan Reynolds', with a long horizontal flourish extending to the right.

Alan Reynolds, Team Leader
Emerging Technologies Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure: Label stamped “notification”

NOTIFICATION

524-613

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

02/07/2019

Plant-Incorporated Protectant Label

COT102 × MON 15985

~~Insect-Protected Cotton~~

~~(Alternate Brand Name: Bollgard® 2)~~

(OECD Unique Identifier: ~~SYN-IR102-7 × MON-15985-7~~)

Active Ingredients:

Bacillus thuringiensis Vip3Aa19 protein and the genetic material necessary (vector pCOT1) for its production in event COT102 cotton (~~OECD Unique Identifier SYN-IR102-7~~).....≤ 0.00051%*

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary (vector PV-GHBK11) for its production in event MON 15985 cotton (~~OECD Unique Identifier MON-15985-7~~).....≤ 0.0540%*

Bacillus thuringiensis Cry1Ac protein and the genetic material necessary (vector PV-GHBK04) for its production in event MON 15985 cotton (~~OECD Unique Identifier MON-15985-7~~).....≤ 0.00059%*

Other Ingredients:

Hygromycin B phosphotransferase (APH4), marker protein, and the genetic material necessary (vector pCOT1) for its production in event COT102 cotton (~~OECD Unique Identifier SYN-IR102-7~~).....≤ 0.00007%*

Neomycin phosphotransferase II (NPTII), marker protein, and the genetic material necessary (vector PV-GHBK04) for its production in event MON 15985 cotton (~~OECD Unique Identifier MON-15985-7~~).....≤ 0.00061%*

β-glucuronidase protein (GUS), marker protein, and the genetic material necessary (vector PV-GHBK11) for its production in event MON 15985 cotton (~~OECD Unique Identifier MON-15985-7~~).....≤ 0.0066%*

* Percentage (wt/wt) on a dry weight basis.

KEEP OUT OF REACH OF CHILDREN

CAUTION

~~Net (Contents)~~=====

~~® Bollgard is a registered trademark of Monsanto Technology LLC.~~

EPA Registration Number 524-613
EPA Establishment Number 524-MO-002
Monsanto Company
800 North Lindbergh Blvd.
St. Louis, Missouri 63167

NET CONTENTS

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Cotton has been transformed to express the *Bacillus thuringiensis* subsp. *Kurstaki* (*B.t.*) delta endotoxins Cry1Ac, Cry2Ab2, and *Bacillus thuringiensis* (*B.t.*) Vip3Aa19 protein for the control of the following lepidopteran cotton insect pests:

This product controls or suppresses the following cotton lepidopteran insect pests:

Tobacco Budworm	<i>Heliothis virescens</i>
Pink Bollworm	<i>Pectinophora gossypiella</i>
Cotton Bollworm	<i>Helicoverpa zea</i>
Cabbage Looper	<i>Trichoplusia ni</i>
Saltmarsh Caterpillar	<i>Estigmene acrea</i>
Cotton Leaf Perforator	<i>Bucculatrix thurbeiella</i>
Soybean Looper	<i>Pseudoplusia includens</i>
Beet Armyworm	<i>Spodoptera exigua</i>
Fall Armyworm	<i>Spodoptera frugiperda</i>
Yellowstriped Armyworm	<i>Spodoptera ornithogolli</i>
European Corn Borer	<i>Ostrinia nubilalis</i>

Transformed cotton must be accompanied by the Grower Guide, which contains the following information:

1. The *B.t.* proteins expressed in this cotton control the above listed lepidopteran cotton insect pests.
2. Routine applications of insecticides to control these insects are usually unnecessary when cotton containing the *B.t.* proteins is planted.
3. Instruction for growers to read the product Grower Guide prior to planting for information on planting, production, and insect-resistance management.
4. This product must not be planted nor sold for commercial planting in Hawaii, Puerto Rico, U.S. Virgin Islands, and south of Route 60 (near Tampa) in Florida.

The following information regarding test plots and seed production must be displayed on bags ~~bag tags~~ of COT102 × MON 15985 cotton seed intended for these purposes:

- a) Test plots or breeding nurseries, regardless of the plot size, established in Hawaii must not be planted within three miles of *Gossypium tomentosum* and must be surrounded by 24 border rows of a suitable pollinator trap crop.
- b) Experimental plots and breeding nurseries of COT102 × MON 15985 cotton are prohibited on the U.S. Virgin Islands, and
- c) Test plots or breeding nurseries, regardless of plot size, established on the island of Puerto Rico may be established without restriction if insecticide applications are used to effectively mitigate gene flow. Otherwise, established test plots or breeding nurseries, regardless of plot size, established on the island of Puerto Rico must not be planted within three miles of feral cotton and must be surrounded by 24 border rows of a suitable pollinator trap crop.

The following information regarding commercial production must be included in the Grower Guide:

In the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler, all growers of COT102 × MON 15985 cotton must employ one of the following structured refuge options:

1) External, Unsprayed Refuge

Ensure that at least 5 acres of non-*Bt* cotton (refuge cotton) are planted for every 95 acres of this product (total of 100 acres). The size of the refuge must be at least 150 feet wide, but preferably 300 feet wide. This refuge may not be treated with sterile insects, pheromone, or any insecticide (except listed below) labeled for the control of tobacco budworm, cotton bollworm, or pink bollworm. At the pre-squaring cotton stage only, the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars. At the pre-squaring cotton stage only, the refuge may be treated with acephate or methyl parathion at rates which will not control tobacco budworm or the cotton bollworm (equal to or less than 0.5 lb of active ingredient per acre). The variety of cotton planted in the refuge must be comparable to this product, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, terminations, and management of other pests) similarly to this product. Ensure that a non-*Bt* cotton refuge is maintained within at least ½ linear mile (preferably adjacent to or within 1/4 mile or closer) from the COT102 × MON 15985 fields.

2) External Sprayed Refuge

Ensure that at least 20 acres of non-*Bt* cotton (refuge cotton) are planted for every 80 acres of this product (total of 100 acres). The variety of cotton planted in the refuge must be comparable to this product especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, terminations, and management of other pests) similarly to this product. The non-*Bt* cotton may be treated with sterile insects, insecticides (excluding foliar *Bt* products), or pheromones labeled for control of the tobacco budworm, cotton bollworm, or pink bollworm. Ensure that a non-*Bt* refuge is maintained within at least 1 linear mile (preferably within ½ mile or closer) from the COT102 × MON 15985 cotton fields.

3) Embedded Refuge

Plant the refuge cotton as at least one single non-*Bt* cotton row for every six to ten rows of this product. The refuge may be treated with sterile insects, any insecticide (excluding foliar *Bt* products), or pheromone labeled for the control of pink bollworm whenever the entire field is treated. The in-field refuge rows may not be treated independently of the surrounding *Bt* cotton field in which it is embedded. The refuge must be managed (fertilizer, weed control, etc.) identically to the COT102 × MON 15985 cotton. There is no field unit option.